

Director's Report to the National Advisory Council on Drug Abuse

September 5, 2018

Nora D. Volkow, M.D., Director

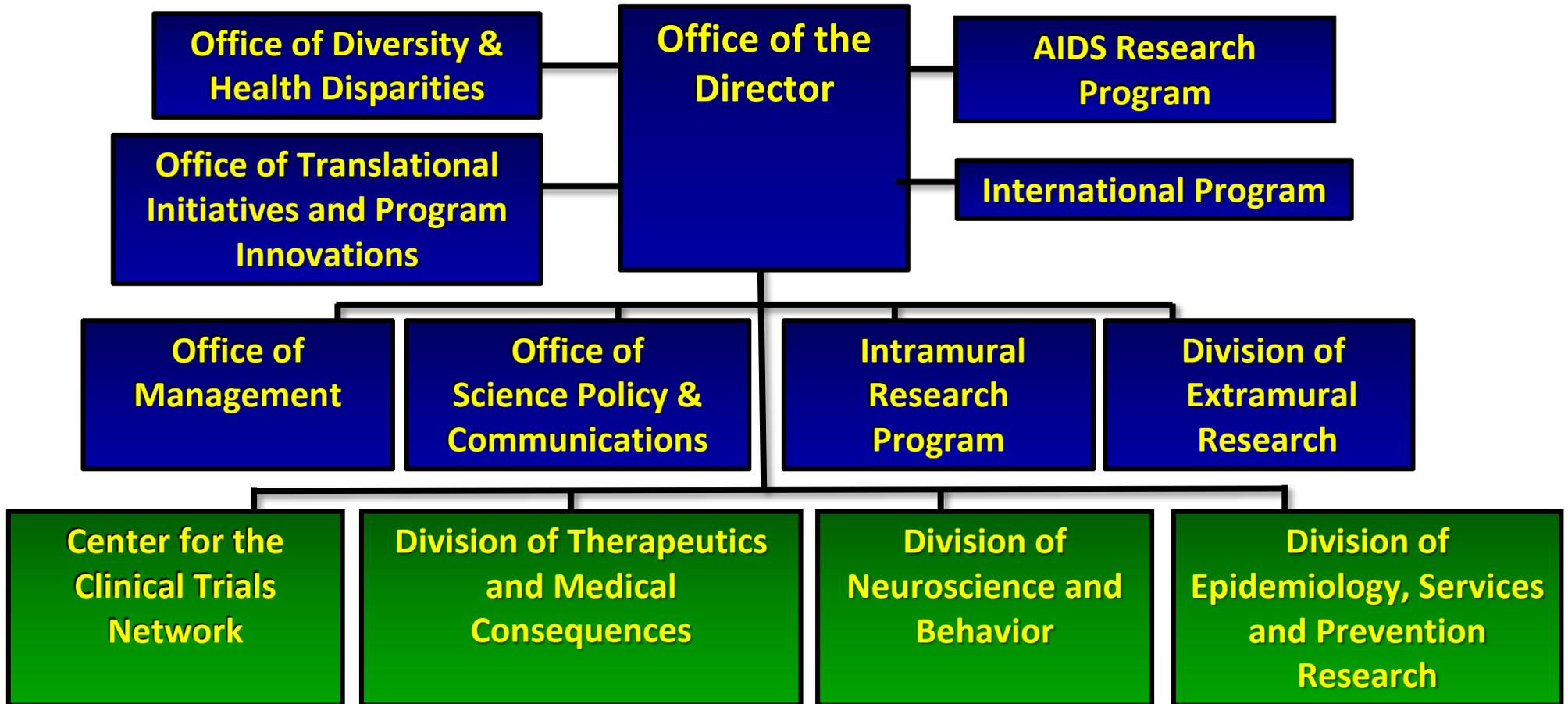


National Institute
on Drug Abuse



@NIDAnews

NIDA



Director's Report to the National Advisory Council on Drug Abuse

- Budget Update**
- What's New @ HHS/NIH?**
- Recent NIDA
Activities & Events**

NIDA BUDGET

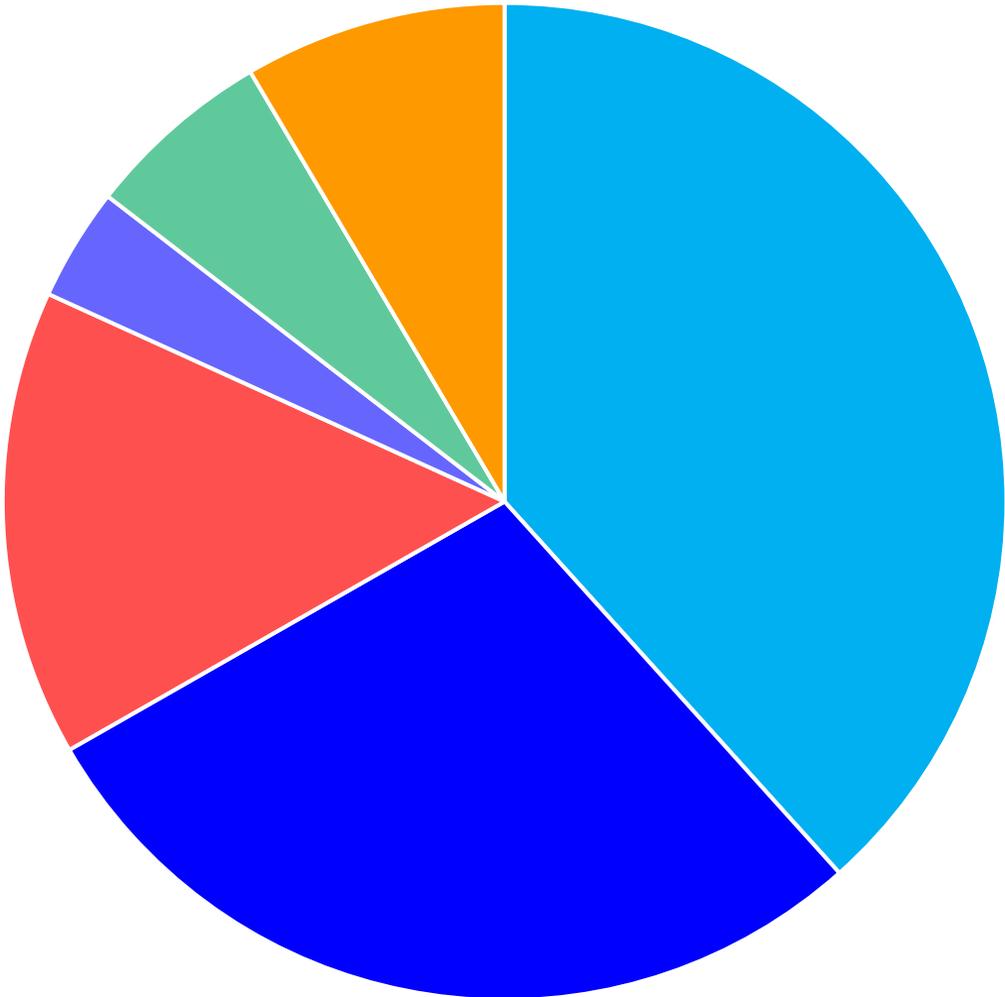
(Thousands)

	FY 2017 Actuals	FY 2018 Operating Plan	FY 2018 Opioid Funding¹	FY 2019 President's Budget
NonAIDS	\$794,102	\$858,106	\$250,000	
AIDS	\$276,711	\$268,551		
TOTAL	\$1,070,813	\$1,126,657	\$250,000	\$1,137,403

¹ *FY 2018 Opioid Funding expires September 30, 2019*

National Institute on Drug Abuse Portfolio

FY 2017 Actual



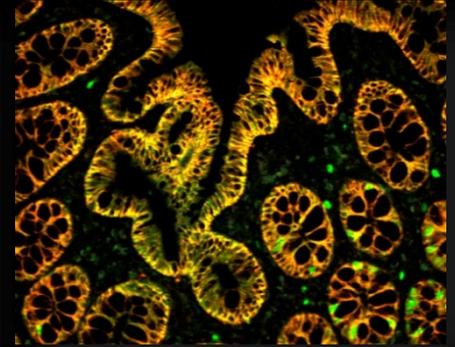
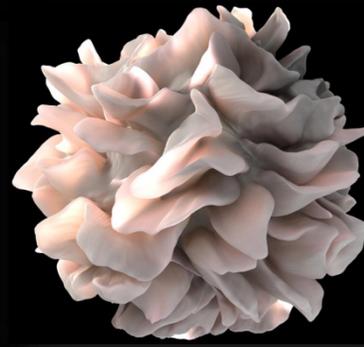
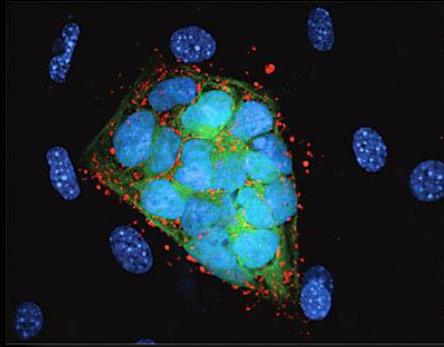
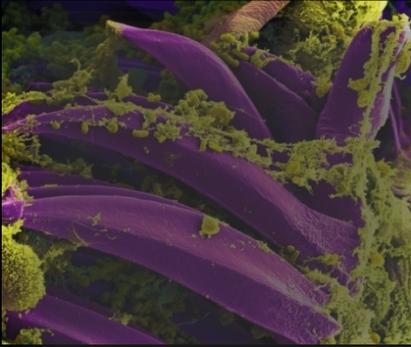
- Division of Neuroscience & Behavior -- 38%
- Division of Epidemiology, Services & Prevention Research -- 28%
- Division of Therapeutics and Medical Consequences -- 15%
- Center for the Clinical Trials Network -- 4%
- RMS -- 6%
- Intramural Research -- 8%

Director's Report to the National Advisory Council on Drug Abuse

- **Budget Update**

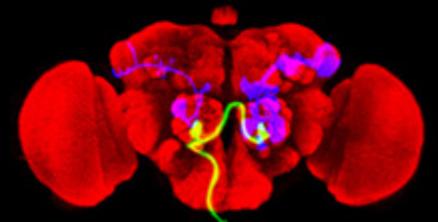
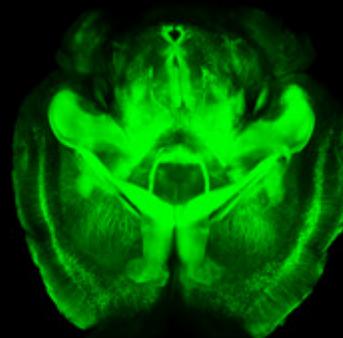
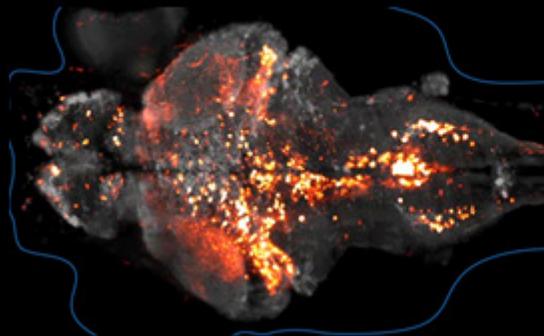
- **What's New @ HHS/NIH?**

- **Recent NIDA
Activities & Events**



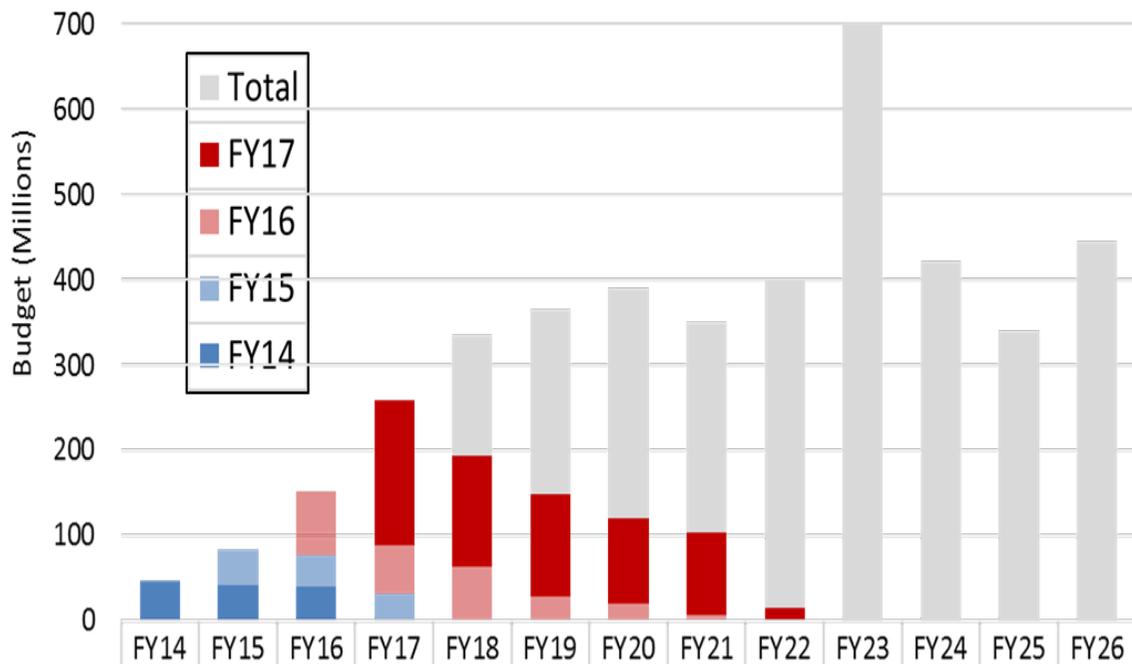
BRAIN...

***mapping brain activity at the
speed of thought***



THE BRAIN INITIATIVE®

	New (FY2017)	Since BRAIN Began (FY2014)
Number awards	110	345
Number investigators	178	504
Investment	\$169.6M	\$548.3M



Awarded and committed BRAIN Initiative funds as of FY2017.

Gray represents anticipated funds for the remainder of the initiative, assuming a “base” budget of \$150M (now ~\$310) plus funds authorized by the 21st Century Cures Act.

- NIH BRAIN Director - Search Committee has recommended a short list for leadership to review



BRAIN Update

Home | About the BRAIN Initiative® | NIH

NINDS Seeking Exceptional Candidates for the Position of Director of the NIH BRAIN Initiative

NIHNINDS | JUNE 23, 2016 | SCIENCE

The National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), is recruiting for the position of Director of the NIH Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative...



Anne Churchland @anne_churchland Following

Who aims to shape the future of #neuroscience ? @NINDSdirector just announced #NIH seeks #BRAIN Initiative director

Walter J. Koroshetz @NINDSdirector
#NIH seeks visionary scientist to Direct #BRAIN Initiative, apps reviewed starting Aug 8: 1.usa.gov/28QXgzO

RETWEETS 9 | LIKES 7

6:38 AM - 27 Jun 2016

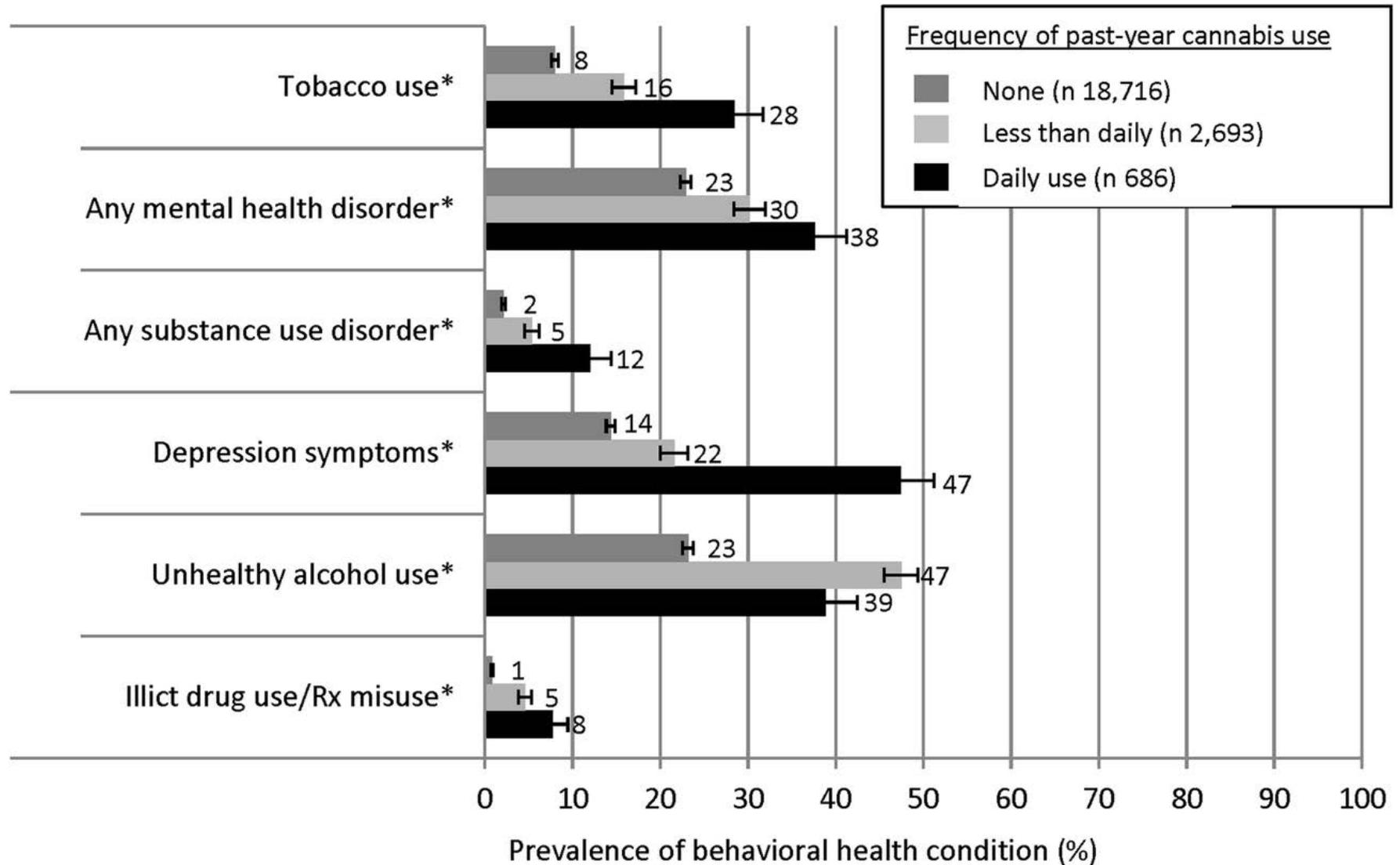
www.braininitiative.nih.gov

Director's Report to the National Advisory Council on Drug Abuse

- **Budget Update**
- **What's New @ HHS/NIH?**

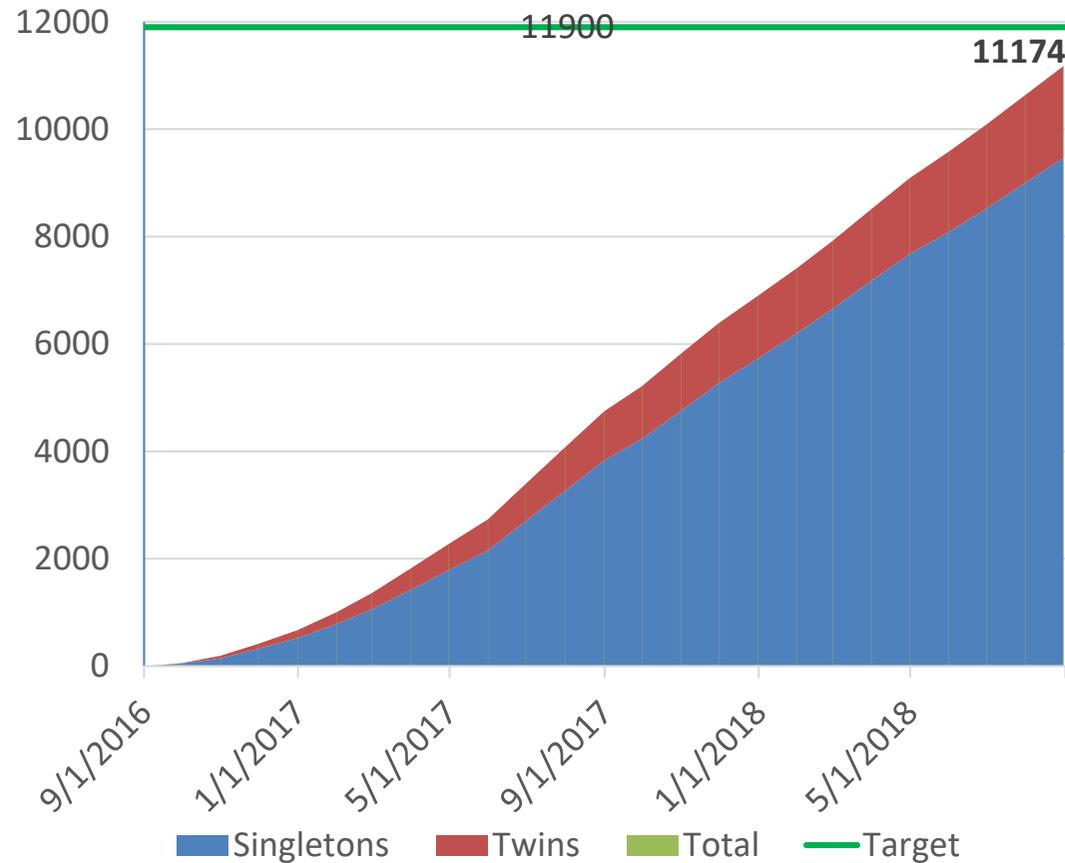
- **Recent NIDA
Activities & Events**

Prevalence Of Behavioral Health Conditions Across Frequency Of Cannabis Use Among Adult Primary Care Patients In Washington State



ABCD Update

ABCD Enrollment As of August 30, 2018



ABCD Target Increase

- *To improve representation of African Americans and lower SES White and Asian families, ABCD target has been increased to 11,900 and enrollment window has been extended to October 15, 2018.*

ABCD Data Release

- *DICOM images from ~8,200 participants currently available.*
- *Interim curated data on first 4,500 participants released February 2018.*
- *Patch data release anticipated mid-October 2018*
- *Data Exploration and Analysis Portal anticipated mid-October 2018*





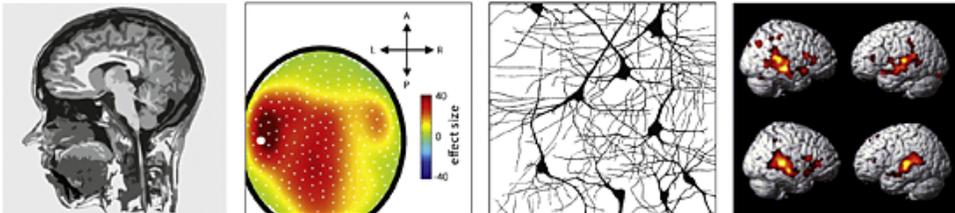
ISSN 1878-9293

Developmental
Cognitive Neuroscience

Special Issue: August 2018

***The Adolescent Brain
Cognitive Development
(ABCD) Consortium:
Rationale, Aims, and
Assessment Strategy***

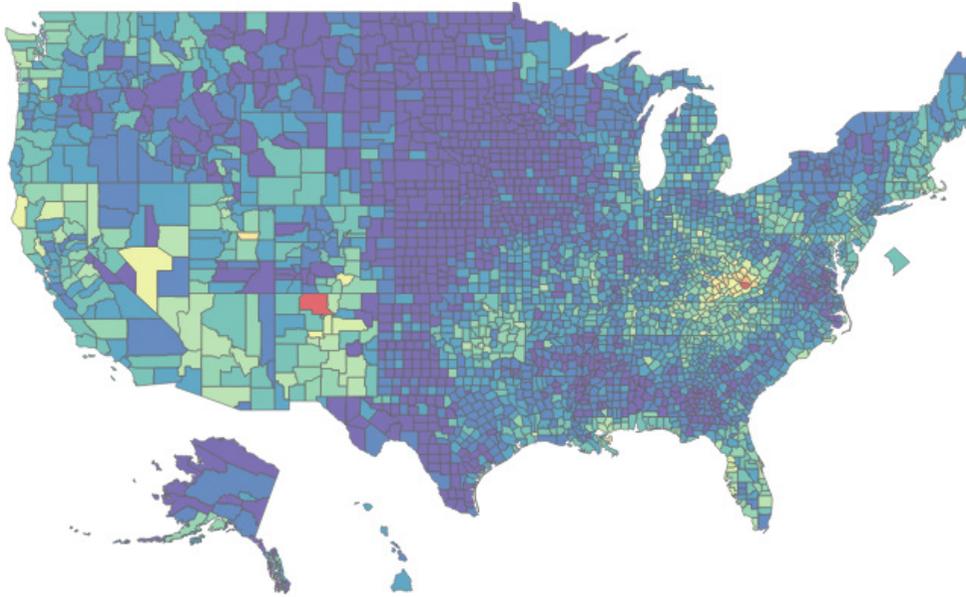
*Edited by Sarah W. Feldstein Ewing,
Monica Luciana Volume 32, Pages 1-164.*



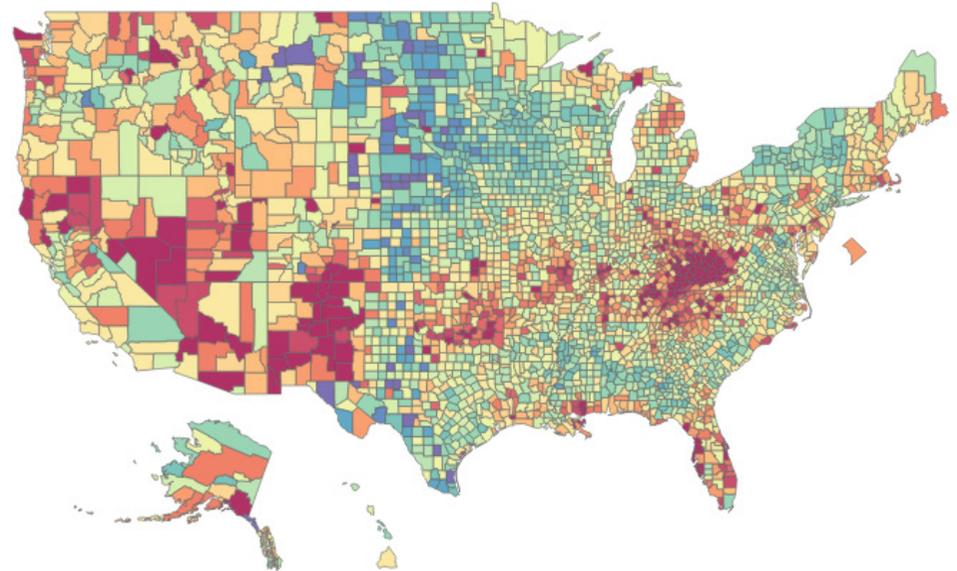
Assessment of the Prodromal Questionnaire–Brief Child (PQ-BC) Version for Measurement of Self-reported Psychotic-like Experiences in Childhood
Karcher, N et al., JAMA Psychiatry. 2018;75(8):853-861.

Overdose Death Rates

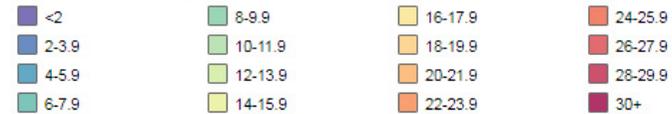
1999



2016



Legend for estimated age-adjusted death rate (per 100,000 population)



Source: <https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/index.htm>

HHS Priority Action Plan: Reduce Opioid Morbidity and Mortality

***1) Expand and improve prevention,
treatment and recovery support services;***



1) Expand availability of naloxone

2) Strengthen public health data and reporting;

3) Support cutting-edge research;

4) Advancing the practice of pain management.

VIEWPOINT

Helping to End Addiction Over the Long-term

The Research Plan for the NIH HEAL Initiative

Francis S. Collins, MD, PhD

National Institutes of Health, Bethesda, Maryland.

Walter J. Koroshetz, MD

National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, Maryland.

Nora D. Volkow, MD

National Institute on Drug Abuse, National Institutes of Health, North Bethesda, Maryland.

Extraordinary focus by all segments of society is required to respond to the nation's opioid crisis. Now is the time to channel the efforts of the scientific community to deliver effective—and sustainable—solutions to this formidable public health challenge. Recognizing this opportunity, Congress added \$500 million to the base appropriation of the National Institutes of Health (NIH), starting in fiscal year 2018.¹ The NIH will invest these much-needed resources to support science that advances national priorities for addiction and pain research² with a bold new trans-NIH initiative called Helping to End Addiction Long-term (HEAL).³ In this Viewpoint, we outline the initial components of this cross-cutting, interdisciplinary program.

More than 25 million US adults are affected by daily pain.⁴ More than 2 million individuals in the United States have an opioid use disorder (OUD), most starting with opioid analgesics prescribed to them or procured from diverted medications, but once addicted, often shifting to illicit heroin or synthetic opioids.⁵ The scope of this crisis is staggering, but scientific advances offer strategies that can help the nation overcome it.

At the National Rx Drug Abuse and Heroin Summit in April 2018, leaders from both the public and private sectors affirmed that research is essential to the effort to end this public health crisis. It will take “all hands on deck” to make this happen, which is why HEAL seeks to foster innovative partnerships with other government agencies, academic institutions, industry, communities, and patient advocates. Through a year-long series of en-

Table. Research Plan for the NIH HEAL Initiative

Opportunities	Components
Improving Treatments for Opioid Misuse and Addiction	
New treatments for addiction	Identify new targets, develop new medications/immunotherapies; reformulate existing medicines
	Improve overdose reversal medicines
	Develop new therapies for opioid-induced respiratory depression
Optimization of effective treatments for addiction	Enhance NIDA Clinical Trials Network for opioid research
	Establish Justice Community Opioid Intervention Network
	Initiate HEALing Communities Study
NOWS	Expand ACT NOW pilot study; use results to conduct clinical trials to determine best practices for clinical care of NOWS
Enhancing Pain Management	
Better understanding of chronic pain	Establish Acute to Chronic Pain Signatures program
New nonaddictive pain treatments	Identify new targets for pain treatment
	Engineer preclinical testing platforms to profile potential nonaddictive treatments
Public-private HEAL Partnership to speed movement of nonaddictive treatments through clinical pipeline	Enhance data and asset sharing
	Validate biomarkers to inform neurotherapeutic and pain clinical research
	Establish clinical trials network to support and accelerate trials of nonaddictive pain therapies

Abbreviations: HEAL, Helping to End Addiction Long-term; NIDA, National Institute on Drug Abuse; NIH, National Institutes of Health; NOWS, neonatal opioid withdrawal syndrome.

NIDA: HEAL - TREATMENT ENHANCEMENTS *Focused Medications Development Research Project*

Despite effective OUD medications their utility is limited due to:

- Low treatment rates
- Adherence challenges
- Increased potency of illicit opioids



Goal is to advance rapidly the development of compounds to prevent and reverse overdose and treat the different stages of OUD including:

- New formulations of existing medications to improve OUD treatment compliance, prevent relapse and reduce diversion
- Stronger, longer-acting opioid antagonist formulations to counteract overdoses
- Interventions to counteract respiratory depression by means other than antagonists
- Novel non-opioid based medications and immunotherapies for OUD
- Medication targeting endpoints other than abstinence (i.e., insomnia, craving, dysphoria).

Medications Development Research Project -- Actions to Date



- Notice ***Change of Requirements*** for RFA-DA-19-002, "Development of Medications to Prevent and Treat OUD and Overdose (UG3/UH3) (Clinical Trial Optional)" [\(NOT-DA-18-016\)](#)
- Notice ***Change of Requirements*** for PAR-18-218, "Strategic Alliances for Medications Development to Treat SUD (R01 Clinical Trial Optional)" [\(NOT-DA-18-018\)](#)
- Notice ***Change of Requirements*** for PAR-18-219, "Grand Opportunity in Medications Development for SUD (U01 Clinical Trial Optional)" [\(NOT-DA-18-019\)](#)

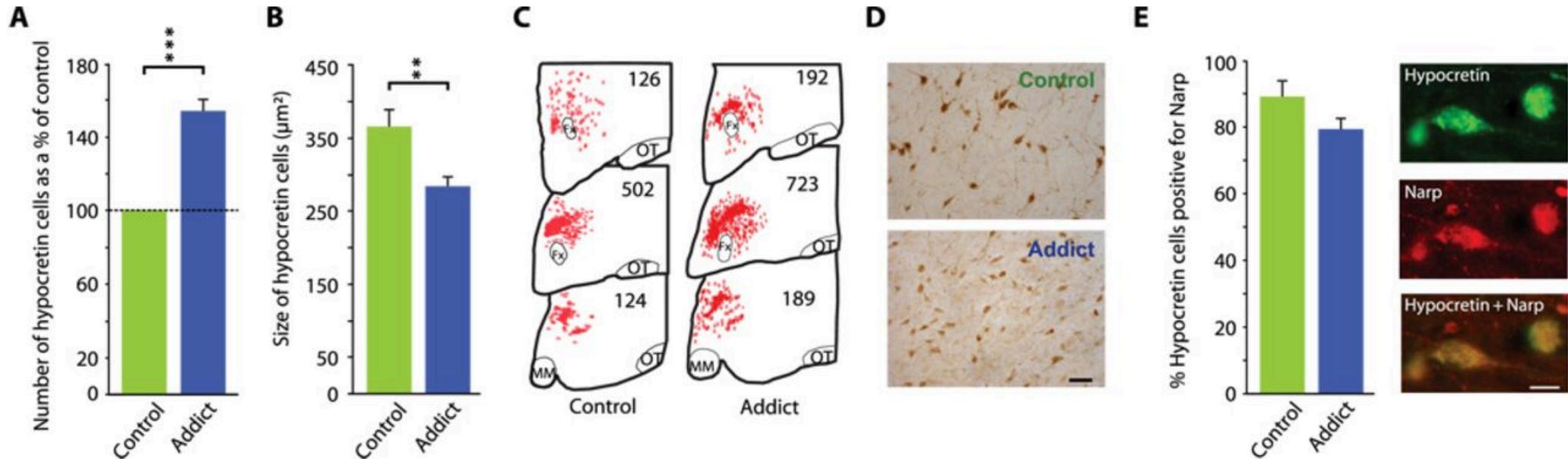
New requirement that for-profit recipients of funds are subject to matching of funds or in-kind contributions of not less than 50 % for research related to OUD.

- Notice of ***Change in Funds Available and Anticipated Number of Awards*** for RFA-DA-19-002, "Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose (UG3/UH3) (Clinical Trial Optional)" [\(NOT-DA-18-020\)](#)

Change from "NIDA intends to commit \$10M in each fiscal year" to "NIDA intends to commit \$70M in each fiscal".

Opiates Increase The Number Of Hypocretin-Producing Cells In Human and Mouse Brain and Reverse Cataplexy In A Mouse Model Of Narcolepsy

Characteristics Of Addicts, Narcoleptic Patients, and Control Subjects



NIDA/SAMHSA: HEAL - *Integrated Treatment* *The HEALing Communities Study*

- ***Implement and evaluate an integrated set of evidence-based prevention and treatment in select communities***
 - Prevent OUD and OD
 - Screen and diagnose
 - Engage and retain in medication-assisted treatment
 - Help sustain long-term recovery
- ***Goal: Decrease OD deaths and OUD***
- ***Partnership with SAMHSA and other federal, state agencies and local communities and Involve: Health care, criminal justice, and community programs***



**Opioid
Cascade
of Care**



The HEALing Communities Study -- Actions to Date

- **RFI HEALing Communities Study NIDA**
- **June 18, 2018, [HEALing Communities Study Design Workshop](#) to solicit feedback from scientific experts, state partners, federal partners, and other stakeholders.**
- **Notice of Intent to Publish a FOA for Data Coordinating Center for the HEALing Communities Study: Developing and Testing an Integrated Approach to Address the Opioid Crisis (UM1) ([NOT-DA-18-025](#))**
- **Notice of Intent to Publish a FOA for Research Site for the HEALing Communities Study: Developing and Testing an Integrated Approach to Address the Opioid Crisis (UM1) ([NOT-DA-18-026](#))**

Estimated Publication Date of FOA: September 17, 2018

First Estimated Application Due Date: December 04, 2018

Earliest Estimated Award Date: February 01, 2019

Earliest Estimated Start Date: February 01, 2019



- **CTN Mission**

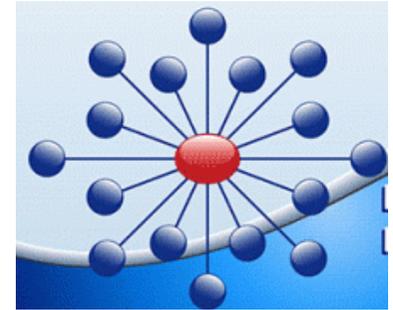
- Develop, validate, refine, and translate into practice new treatment options for SUD

- **Expand the size and scope of the CTN**

- Expand access in primary care, ED and rural areas
- Facilitate implementation science

- **Contribute to improved quality of and access to treatment for OUD**

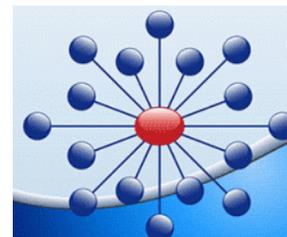
- Introduce sustainable interventions in underserved, highly impacted areas
- Implement OUD treatment practices in general medical settings
- Expand of the OUD treatment clinical and research workforce



Clinical Trials Network Expansion -- Actions to Date

***Notice of Intent to Publish a Funding Opportunity
Announcement for The National Drug Abuse Treatment
Clinical Trials Network (UG1) Clinical Trial Optional
[\(NOT-DA-18-024\)](#)***

***FOA expected to be published in September 2018 with
expected application due date in November 2018.***



NIDA: HEAL - JUSTICE INITIATIVE

Justice Community Opioid Innovation Network (JCOIN)

- **Goal:** Develop a network of researchers collaborating across justice and community-based service settings to transform responses to the opioid crisis
- **Components**
 - **Clinical Research Centers** will execute clinical trials of interventions targeting opioid use in justice populations and settings.
 - Effectiveness and implementation trials encouraged
 - Interventions include medications, technologies, and behavioral interventions
 - **Coordination and Translation Center** will manage logistics, stakeholder engagement, and dissemination of findings and products.
 - Will include empirical translation and dissemination research and training infrastructure
 - **Advanced Analytics and Methodology Resource Center** will provide data infrastructure support across the cooperative.
 - Will include novel research such as modeling studies, national surveys, and systematic collection of changing policies & laws



Justice Community Opioid Innovation Network (JCOIN) -- Actions to Date

- ***NIDA's Justice Priorities are broadly outlined in: Topic DAT18-08: Research on Justice-Involved Populations in the Context of the Opioid Crisis (posted June 25, 2018)***
- ***Awarded a supplement to Chestnut Health Systems to conduct a survey of availability of MAT in jails and prisons. PIs: Christy Scott & Michael Dennis; U01DA036221-05 \$1.19M awarded to date.***
- ***Notice of Intent to Publish FOA for HEAL Justice Community Opioid Innovation Network Advanced Analytics and Methodology Center ([NOT-DA-18-036](#))***
- ***Notice of Intent to Publish FOA for HEAL Justice Community Opioid Innovation Network Coordination and Translation Center ([NOT-DA-18-035](#))***

Estimated Publication Date of FOAs: October 01, 2018

First Estimated Application Due Date: December 01, 2018

Earliest Estimated Award Date: April 01, 2019

Earliest Estimated Start Date: June 01, 2019



HEAL- Understand the Neurobiology of Chronic Pain

Leads: NINDS and NIDA

Common Fund: Acute to Chronic Pain Signatures

Objective biosignatures to identify susceptibility or resilience to chronic pain

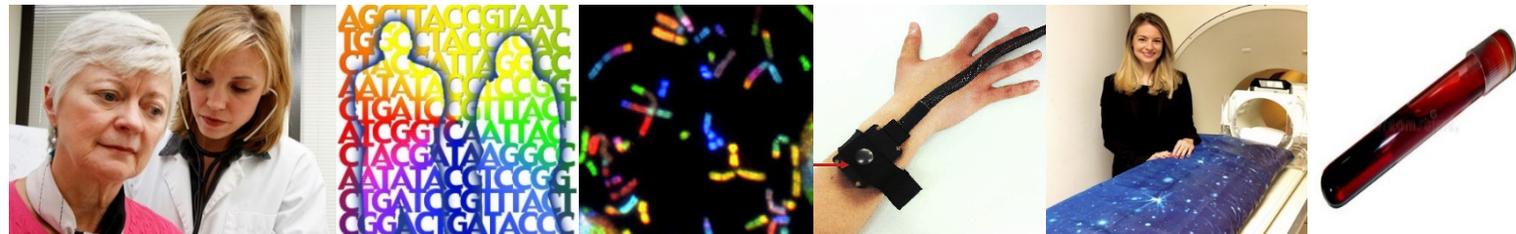
- Phenotyping
- Genotyping

Sensory tests

- Imaging
- -omics

Outcomes

- Mechanisms
- Novel therapeutic targets
- Cohort stratification
- Prevention



NINDS: Discovery and Validation of Biomarkers, Endpoints and Signatures for Pain Conditions

Define patient populations and treatment response to accelerate therapy development

Discovery

Biomarkers, endpoints, signatures

- Quantitative sensory tests
- Neuroimaging
- Circulating markers (omics)
- Phenotypic characteristics
- Genetic
- Diverse pain conditions

Validation

Response, predictive biomarkers

- Retrospective studies
- Pilots
- Prospective studies through **Clinical Trials Network**



NINDS: HEAL-Develop a Clinical Trials Network

Improve quality, consistency, efficiency of pain clinical trials

- Incentivize, accelerate Phase II trials
- Focus on well-defined pain conditions with high-unmet need
- Reduce the time to start, enroll, run, and complete trials
- Test compounds and devices from industry, academia
- Incorporate biomarker studies
- Accommodate other platform trial designs



[NOT-NS-18-069](#); [NOT-NS-18-057](#); [NOT-NS-18-058](#)

Priority Areas

Prevention Research

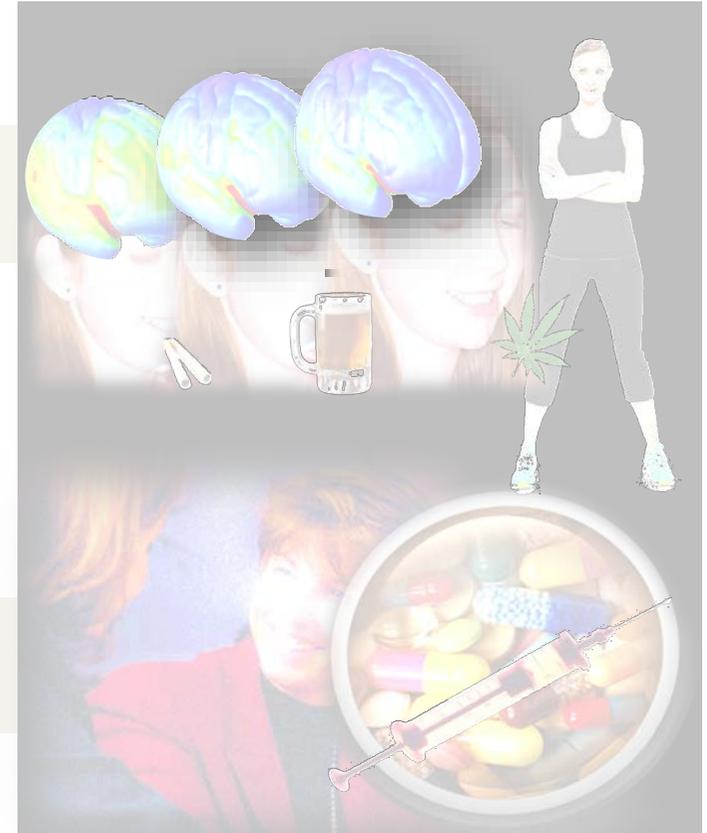
(Children & Adolescents)
genetics/epigenetics
development
environment
co-morbidity

Treatment Interventions

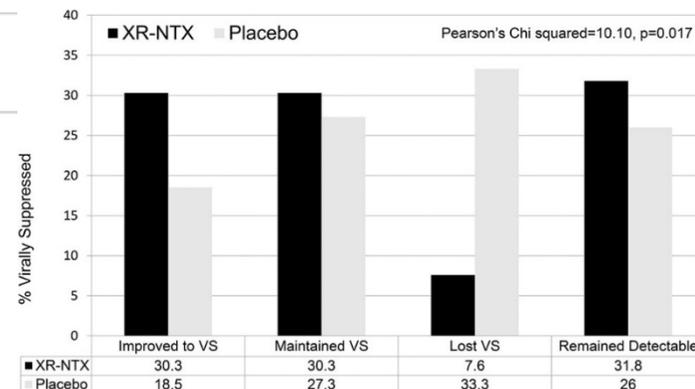
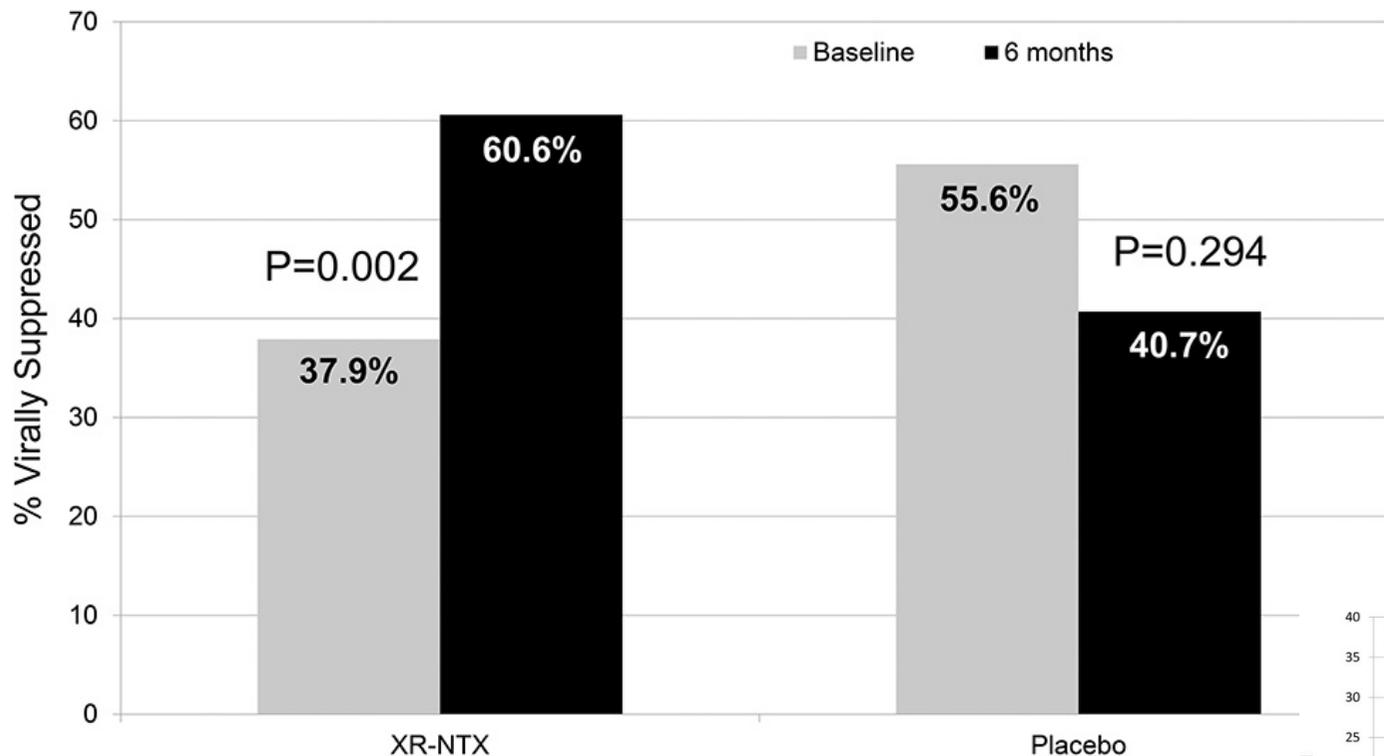
(New Targets & New Strategies)

HIV and Drugs

Prevention
Treatment



Extended-Release Naltrexone Improves Viral Suppression Among Incarcerated Persons Living With HIV With Opioid Use Disorders Transitioning to the Community



*Discordant Outcomes:
McNemar's chi-squared = 4.1724, df = 1, p = 0.041

2018 Intel International Science and Engineering Fair Addiction Science Awards

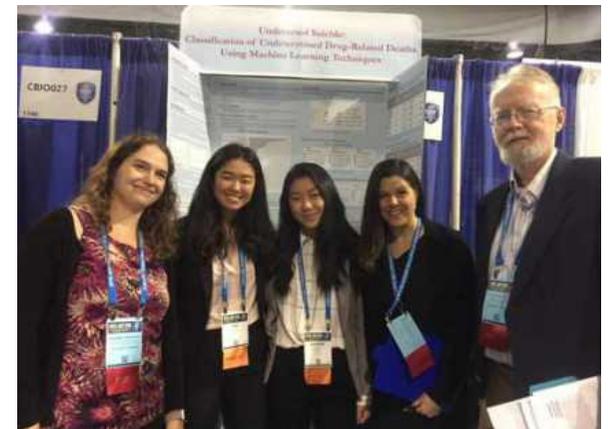
Mia Yu (17) and Daphne Liu (14) from West High School in Salt Lake City
Undetected Suicide: Classification of Undetermined Drug-Related Deaths Using Machine Learning Techniques



Rohan Arora (17), Venkat Krishnan (17), and Anil Tolwani (18) from
American High School in Fremont, California
LabTrak: A Micro-Telemetry Device for Modeling Mice Behavior



Saadh Ahmed (17) from Northview High
School in Johns Creek, Georgia
*Development of a Drug-Likeness Rule for
Natural Products*



2018

THE NATIONAL INSTITUTE ON DRUG ABUSE &
THE NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
PRESENT

FRONTIERS IN ADDICTION RESEARCH

NIDA-NIAAA Mini-Convention

Friday, November 2, 2018 • 8:30 AM – 5:30 PM

San Diego Convention Center – Room 7AB – San Diego, CA

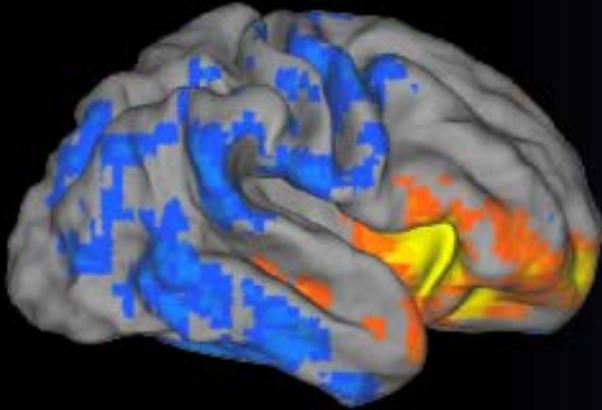


Image Courtesy of Dr. Cynthia Rogers



Cutting-edge Topics in Addiction Research

Three scientific sessions will explore:

- 1) Data Science – New Paradigms for Addiction Research*
- 2) Effects of Early Life Adversity on Substance Use Disorder-Related Circuitry*
- 3) Novel Opioid Receptor Signaling in Addiction and Pain*

2018 Jacob P. Waletzky Memorial Award Lecture

NIDA-NIAAA Early Career Investigator Showcase (ECIS)